K111234

MAY 13 2011

4. 510(k) Summary

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Contact:	Robin Intagliata
Date Prepared:	October 18, 2010
Proprietary Name:	Click-It
Common Name:	Ceramic Bracket Orthodontic
Classification Name:	Bracket, Ceramic, Orthodontic 21 CFR 872.5470

Device for Which Substantial Equivalence is Claimed

Ormco Corporation, *Damon 4Clear* (K081415)
Dentsply International, In-Ovation C (K060837)
3M Unitek Corporation, Clarity Modified Ceramic Bracket (K062305)

Device Description

The Click-It ceramic self-ligating bracket is intended to be used in an orthodontic treatment with the aim of moving teeth. The basic function is the same as the orthodontic brackets for which substantial equivalence is claimed such that the movement of the tooth and remodeling of the mandibular and maxillary bone will occur when gentle sustained pressure is applied to the teeth through the bracket and wire system. The Click-It ceramic self-ligating bracket has self-ligating properties and will include maxillary and mandibular brackets from second bicuspid to second bicuspid. The device consists of a polycrystalline alumina bracket with two polycrystalline alumina jaws, a nickel titanium spring and two nickel titanium pins.

The design of a self-ligating bracket enables the archwire to be ligated to the bracket without the use of auxiliary devices such as wires or elastics. It enables quicker archwire placement without any significant change in the mechanics when compared to the devices for which substantial equivalence is claimed.

As its predicates, Click-It ceramic self-ligating bracket enables several types of tooth movements throughout the treatment such as: tipping, translation (bodily movement), torque, extrusion, rotation, and intrusion.

The Click-It ceramic self ligating brackets are bonded to the buccal and labial surface of teeth and enable the orthodontic treatment.

Intended Use of the Device

The Click-It ceramic self-ligating bracket is intended to be used in an orthodontic treatment with the aim of moving teeth.

Technological Characteristics

Click-It can be considered substantially equivalent to the predicate orthodontic products legally marketed. The devices that substantial equivalence is claimed are; *In-OvationC* by Dentsply International, *Clarity Modified Ceramic Bracket* by 3M Unitek Corporation and *Damon 4Clear* by Ormco Corporation as shown in Table 4-1. All the devices with substantial equivalence are ceramic self-ligating brackets intended to be used in an orthodontic treatment with the aim of moving teeth. All the devices with substantial equivalence when used in traditional treatment are bonded to the labial and buccal surfaces of the patient's teeth after which an archwire is ligated into the slot of each bracket. The combination of brackets, archwire and auxiliaries results in corrective forces moving the teeth into optimal position. These positions are partially predetermined by the predefined tips, torques, and In/Out values utilized by the proven treatment prescription such as Roth, MBT or similar industry prescriptions listed in table 4.1 under "Available prescriptions". The ligating mechanism present in these brackets enables self-ligation through the device design, eliminating the need of elastomeric or metallic ligatures. In special cases where self-ligation is difficult to achieve, standard ligatures may be used. Auxiliaries may be used together with the bracket/archwire/ligatures to increase the effectiveness of the orthodontic treatment.

Table 4-1. Product characteristics

Product Name	*Click-It*	*In-OvationC*	*Clarity Modified Ceramic Bracket*	*Damon 4Clear*
510(k) Number	N/A	K060837	K062305	K081415
Class	II	II	II	II
Product Code	NJM	NJM	NJM	NJM
Manufacturer	TP Orthodontics	Dentsply International	3M Unitek Corporation	Ormco Corporation
Intended use	For use in orthodontic treatment with the aim of moving teeth	For orthodontic movement of natural teeth, excluding the mandibular bicuspid teeth	For use in orthodontic treatment	Aid in the movement of patient teeth during orthodontic treatment
Material Composition	Polycrystalline alumina and NiTi	Polycrystalline alumina and rhodium-coated Coballoy	Polycrystalline alumina, stainless steel and NiTi	Polycrystalline alumina and NiTi
Bracket Design	Self-Ligating	Self-Ligating	Self-Ligating	Self-Ligating
Movable (ligating) member	Jaws	Spring clip	Mesial and distal C clips	Sliding door
Standards	ASTM F2063-05 ISO 11405-2003 ISO 10993 SEC 5, 10, 11	Unknown	ASTM F2063-05	ASTM F2063-05
Biocompatibility	Compliant as applicable to ISO 10993	Standard used unknown	Standard used unknown	Standard used unknown
Shear Bond Strength*	Average 12.44 Mpa	Average 5.63 Mpa	Average 16.54 Mpa	Average 6.62 Mpa
Available Slot Sizes	0.022"	0.018", 0.022"	0.018", 0.022"	0.022"
Available Prescriptions	MBT	Roncone, Roth	Ricketts, MBT, Roth	Low, Standard, Super Torque

*Shear Bond Strength tested in accordance with ISO11405

Performance Testing

The Click-It orthodontic appliance has the same intended use as the predicates and similar technological characteristics. Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of ceramic self ligating brackets. The following tests have been conducted:

- Bond strength (ISO 11405:2003 (E)) – Comparison of the shear bond strength of the Click-It and predicate devices. The performance of Click-It brackets were determined to have comparable shear bond strength to the predicate devises. De-bonding of Click-It

brackets was found not to cause any enamel damage and performs as the predicate devises.

- Friction test – Comparison of the wire to bracket frictional characteristics of the Click-It and predicate devices. Data analysis determined that Click-It ranks second out of the four bracket systems tested, closely following Clarity SL and outperforming both Damon 4Clear and In-Ovation C.
- Escapement test – Comparison of wire escapement characteristics of the subject and predicate devices. The Click-It brackets performed as expected in a manner similar to the predicate devices. Click-It brackets were found to retain the wires in normal orthodontic procedures. More severe case will require additional ligatures.
- Impact test – Comparison of the catastrophic disassembly of the subject and predicate devices should the brackets fail from an impact. The Click-It bracket broke in such a manner not to cause the patient harm. The broken parts were of sufficient size to be easily expelled from the mouth. Any particles that cannot be seen by the naked eye could be ingested and expelled without harm to the patient. The Click-It bracket performed as expected fracturing in a manner that does not impart shards into the patient's mouth and failed in a similar fashion to the predicate devices.
- Pull test – Comparison of the bracket/bond performance of the subject and predicate devices. The Click-It bracket de-bonded by the bond failing in shear at the bracket/adhesive interface. This is how a bracket should fail and the Click-It performed as well as or better then the predicate devices. The Click-It brackets also meet the predefined acceptance criteria set forth in the testing.
- Archwire Slot Dimensional Comparison– Comparison of the archwire slot characteristics of the subject and predicate devices. The Click-it bracket is dimensionally similar to the predicate devices and conforms to the design specification. The archwire slot is of a design that will allow the Click-It to perform properly.

Test results demonstrated that the Click-It ceramic self ligating brackets comply with the predetermined requirements and preformed similar to predicate devices.

Biocompatibility Testing

Click-It was found to meet the biocompatibility requirements set forth in the appropriate sections of ISO 10993. The click-It bracket meets applicable biocompatibility requirements as listed in section 14 and is safe for use.

Safety and Effectiveness Conclusion

Based on the comparison of devices and performance testing results, TP Orthodontics, Inc. concludes that the Click-It device is safe and effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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TP Orthodontic, Incorporated
C/O Ms. Paula Wilkerson
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K111234
Trade/Device Name: Click-it
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Brackets
Regulatory Class: II
Product Code: NJM
Dated: April 29, 2011
Received: May 2, 2011

Dear Ms. Wilkerson:

This letter corrects our substantially equivalent letter of May 13, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use

510(k) Number (if known): K111234

Device Name: Click-It

Indications For Use:

The Click-It ceramic self-ligating bracket is intended to be used in an orthodontic treatment with the aim of moving teeth.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
.ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

!0(k) Number: K111234